V. 510(k) SUMMARY

APR 21 2003

Submitted by:	T-Scientific, Inc. 1146 Gardencrest Ln. Houston,TX.77077 Phone: 713-302-0019 Fax: 281-587-2299
Contact Person:	Dennis Metcalf
Date Prepared:	January 15, 2003
Proprietary Name:	T-Scientific **T-Pad™**
Common Name:	Liquid Bandage (KMF)
Classification:	Class I: 21 CFR §: 880.5090
Classification Name:	Liquid Bandage (KMF)
Predicate Device:	Marine Polymer Technologies K972914 Syvek Patch Marine Polymer Technologies K984177 Syvek Patch
Device Description:	The T-Scientific **T-Pad™** is a soft, non-woven pad of poly-N-acetylglucosamine. **T-Pad™** is packed in a foil pouch and sterilized by E-beam radiation to a 10^{-6} SAL.
Intended Use:	The T-Scientific **T-Pad™** is intended for use in the local management of bleeding wounds such as lacerations, abrasions, nose bleeds, vascular access site, percutaneous catheters or tubes and surgical debridement, and the promotion of rapid control of bleeding in patients following hemodialysis and in patients on anticoagulation therapy.
Technological Characteristics:	The T-Scientific **T-Pad™** technological characteristics are the same as the Marine Polymer Technologies predicate devices. The T-Scientific **T-Pad™** works in the same manner as the approved predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2003

Mr. Dennis Metcalf
Director of Regulatory Affairs
and Quality Assurance
T-Scientific, Inc.
1146 Gardencrest Lane
Houston, Texas 77077

Re: K030334
Trade/Device Name: T-Pad™
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 15, 2003
Received: January 31, 2003

Dear Mr. Metcalf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Statement of Indications for Use K030334

Applicant: T-Scientific, Inc.
1146 Gardencrest Ln.
Houston, TX. 77077
713-302-0019
Fax:281-587-2299

510(k) Number: _____

Device Name: **T-Pad™**

Indications For Use: The T-Scientific **T-Pad™** is intended for use in the:

1. Local management of bleeding wounds such as lacerations, abrasions, nose bleeds, vascular access site, percutaneous catheters or tubes and surgical debridement, and
2. The promotion of rapid control of bleeding in patients following hemodialysis and in patients on anticoagulation therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030334

Prescription Use X or Over-the-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)